



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,707	07/06/2001	Roger E. Darois	D0188/7126	4890

7590 12/19/2006  
Jason M. Honeyman  
Wolf, Greenfield & Sacks, P.C.  
Federal Reserve Plaza  
600 Atlantic Avenue  
Boston, MA 02210

EXAMINER
----------

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
----------	--------------

3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/900,707	DAROIS ET AL.	
	Examiner	Art Unit	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 46-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 53,56,65,68,71 are rejected under 35 U.S.C. 102(b) as being anticipated by Meier (3416524). Meier shows (Fig. 2) a surgical repair material comprising a fabric **15**, a barrier layer **14** and an edge barrier **12**. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure.

Regarding claims 56,68, Meier discloses the fabric layer can be polypropylene, col. 2, lines 1-5. Fig. 1 clearly shows a mesh structure. Meier discloses the edge barrier is made of an inert material and thus would inhibit the formation of adhesions.

Claims 46,47,50,54-56,59-62,65-68,71 are rejected under 35 U.S.C. 102(b) as being anticipated by Mulhauser et al. (5695525). Mulhauser shows (Figs. 4a,4b) a surgical repair material comprising a fabric **34**, a barrier layer **36** and an edge barrier **32**. Mulhauser additionally illustrates in Figs. 2a,2b,3h the frame structure located at the edge to form an edge barrier. Regarding claims 50,56,62,68, Mulhauser discloses the fabric mesh can be polypropylene, col. 4, lines 37-40. Mulhauser additionally discloses the mesh fabric and barrier layer can be joined by sewing or stitches, col. 5, lines 48,49. The examiner asserts that the claimed physical properties are present in the prior art material (edge barrier) to some extent even though they are not explicitly recited.

Therefore, the examiner hereby burdens the applicant to show that these properties are

Art Unit: 3738

not present in the prior art. Mulhauser discloses that the frame or edge barrier is solid or rigid to provide support to the fabric (col. 4, lines 22,23) and thus would inhibit adhesions from forming.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 48,49,51,52,57,58,63,64,69,70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulhauser et al. '525 in view of Gianturco (5258000).

Mulhauser is explained supra. However, Mulhauser fails to disclose the stitching pattern about the outer peripheral edge or that the barrier material is PTFE. Gianturco teaches that peripheral edge stitching is done to strengthen the repair device, col. 5, lines 20-22. Gianturco also teaches that PTFE is used because it prevents tissue ingrowth used in repairing sensitive tissue and organs, col. 5, lines 27-32. It would have been obvious to one of ordinary skill in the art to incorporate stitches at the peripheral edges for greater support of the repair material and use PTFE for its inhibition of tissue adhesion as taught by Gianturco with the repair device of Mulhauser such that it improves the strength of the tissue in the weakened area of repair.

***Terminal Disclaimer***

The terminal disclaimer filed on 9/21/06 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US

Art Unit: 3738

6258124 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Response to Arguments***

Applicant's arguments filed 9/21/06 have been fully considered but they are not persuasive. Applicant argues that the embodiment shown in Figs. 4a,4b of Mulhauser does not have the edge barrier covering or isolating the fabric edge. However, it should be noted that the support frame **32** clearly isolates a portion of the edge or covers a portion of the edge since the claims do not set forth what an edge is defined as. Since the claims do set forth any special definition of an "edge" it can be construed that since Mulhauser's frame is at the outer periphery of the fabric it is covering or isolating the edge. As admitted in the arguments by the Applicant and above, Mulhauser's Figs. 2a,2b,3h show the frame can be at the outer most periphery, however, this argument would also be moot even if claimed. Applicant states a material having a porosity of 10 $\mu$ m or more is not adhesion resistant, but can promote adhesions. In response to applicant's argument that both Meier and Mulhauser fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., porosity less than 10 $\mu$ m) are not recited in the rejected claim(s). However, it should be noted that this limitation is not supported by the disclosure and thus the Examiner is entitled to give terms in a claim its plain meaning as interpreted by one of ordinary skill in the art. It is noted that the specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an

explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851,1854 (Fed. Cir. 2001) and MPEP 2111.01. Since the disclosure fails to define any special porosity for the edge barrier, it can be said that since both Meier's and Mulhauser's edge barriers are solid materials and not of an open structure they clearly can prevent adhesions.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 6:30am to 4pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738



**BRIAN E. PELLEGRINO**  
**PRIMARY EXAMINER**